K131792

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DEC 16 2013

510(k) Summary -- SyntheCel® Dura Onlay

Date Prepared	November 13, 2013
Submitter	Synthes 1301 GOSHEN PARKWAY West Chester, PA 19380 United States of America
Contact	Heather L. Guerin, Ph.D., P.E. guerin.heather@synthes.com phone: (610) 719-5432
Device Name	SyntheCel® Dura Onlay
Classification	21 CFR 882.5910 (Dura Substitute)
Device Class	2
Product Code(s)	GXQ
Predicate Devices	SyntheCel Dura Replacement Devices (K113071)
Device Description	SyntheCel® Dura Onlay is composed of biosynthesized cellulose and water with a unique construction of non-woven, interconnected cellulose fibers. SyntheCel® Dura Onlay functions as a mechanical layer which protects and repairs the dural defect while preventing further CSF leakage. SyntheCel® Dura Onlay is immunologically inert and has demonstrated minimal foreign body response. It is non-resorbable.
Indications for Use	SyntheCel® Dura Onlay is intended for use as a dura replacement for the repair of dura mater in adults.
Technological Characteristics	See table below

	SyntheCel® Dura Onlay (K131792)	SyntheCel Dura Replacement Devices (K113071)
Indications for Use	SyntheCel® Dura Onlay is intended for use as a dura replacement for the repair of dura mater in adults.	SyntheCel® is intended for use as a dura replacement for the repair of dura mater. SyntheCel® Dura Onlay is indicated for use in adults for the repair of dural defects and it can be placed without sutures. SyntheCel® Dura Substitute is indicated for use in adults for the repair of dural defects and it can be sutured

			into place.
	Contra-indications	Must not be implanted in patients who have known allergy or sensitivity to the implant materials (cellulose).	Same
	Material	Biosynthesized cellulose	Same
	Dimensions	1in x 1in (2.5cm x 2.5cm) 1in x 3in (2.5cm x 7.5cm) 2in x 2in (5.0cm x 5.0cm) 3in x 3in (7.5cm x 7.5cm) 4in x 5in (10.0cm x 12.0cm)	Same.
	Function	Conforms to contours of brain.	Same
	Resorbability	Non-resorbable	Same
	Sterilization	Sterilized by irradiation	Same
Clinical Performance Data	No new clinical performance data were collected in support of this submission. Clinical data were previously collected to evaluate the safety and effectiveness of the SyntheCel® Dura Replacement Devices (including SyntheCel® Dura Repair and SyntheCel® Dura Onlay) as compared to the Control. This data was included in K113071. The SyntheCel® Dura Replacement Devices (including SyntheCel® Dura Repair and SyntheCel® Dura Onlay) were demonstrated to be substantially equivalent to other legally marketed dura replacement products in terms of safety and efficacy.		
Non-Clinical Performance Data	No new non-clinical performance data were collected in support of this submission. Mechanical testing data were previously collected to support substantial equivalence of SyntheCel® Dura Onlay to predicate devices. This data was included in K113071. Tensile strength, and burst strength were tested and SyntheCel® Dura Onlay was demonstrated to be substantially equivalent to predicate devices. Biocompatibility testing according to standards set forth in ISO 10993 previously demonstrated that the material is non-irritating, non-sensitizing, non-mutagenic, non-cytotoxic, non-hemolytic, and non-pyrogenic. This data was included in K113071. Pyrogenicity was evaluated using the Limulus Amebocyte Lysate (LAL) test on the final sterilized SyntheCel® device and found to be less than 0.06 EU/ml (Endotoxin Units / ml) per FDA's Guidance Document for Dura Substitute Devices.		

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Substantial Equivalence to Predicate Devices	Based on the information presented in this submission, the proposed changes to SyntheCel® Dura Onlay do not raise new questions of safety and effectiveness. Therefore, it can be concluded that the SyntheCel® Dura Onlay is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

Synthes® (USA)
% Heather Guerin, Ph.D., P.E.
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, PA 19380

Re: K131792
Trade/Device Name: SyntheCel® Dura Repair and SyntheCel® Dura Onlay
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: November 13, 2013
Received: November 14, 2013

Dear Dr. Guerin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos Peña, Ph.D.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131792

Device Name: SyntheCel® Dura Repair and SyntheCel® Dura Onlay

Indications For Use:

SyntheCel® Dura Repair is intended for use as a dura replacement for the repair of dura mater in adults.

SyntheCel® Dura Onlay is intended for use as a dura replacement for the repair of dura mater in adults.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S